

Remarks

Reconsideration of this Application is respectfully requested.

The specification has been amended to correct obvious typographical errors. The error regarding use of the symbol "°" instead of "°" to represent degrees Celsius would have been obvious to one skilled in the art, as would the correction of that symbol. This is particularly true upon reading the preceding sentences, as well as the rest of the sentence in which the error appears. Furthermore, the symbol "~" was replaced by the word "about." One of skill in the art would have been aware that the "~" symbol represents the word "about."

Claims 2, 3, 14, and 15 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein, claims 1, 4-6, 13, 16-19, and 33 are sought to be amended, and new claims 34-62 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested. Upon entry of the foregoing amendment, claims 1, 4-13, and 16-62 are pending in the application, with 1, 13, and 33 being the independent claims.

Claims 4, 5, 16, and 17 have been amended to correct a spelling error by replacing "zeolyte" with "zeolite." The spelling error would have been obvious to one of skill in the art, as would the correct spelling. Support for this amendment is also found, for example, in the specification at page 5, line 1. Claim 19 has been amended to remove the zeolites recited therein. This error would have been obvious to one of skill in the art, as would its

correction, since the claim recites an acidic ion exchange resin. Support for this amendment is also found for example, in the specification at page 5, lines 1-8.

Support for the other amendments to the claims can also be found throughout the specification and in the claims as originally filed. In particular, support for the amendment to claim 1 can be found, for example, in the specification at page 4, lines 1-2; page 4, lines 20-22; page 5, lines 1-8; page 8, lines 11-12; page 9, lines 4, 12, and 20; and page 10, lines 7 and 16. Support for the amendments to claims 4, 5, 6, 16, 17, and 18 can be found, for example, in the specification at page 4, lines 20-22; page 5, lines 1-8; page 8, lines 11-12; page 9, lines 4, 12, and 20; and page 10, lines 7 and 16. Support for the amendment to claim 13 can be found, for example, in the specification at page 4, lines 1-2; page 4, line 20 to page 5, line 8; page 8, lines 11-12; page 9, lines 4, 12, and 20; and page 10, lines 7 and 16. Support for the amendment to claim 33 can be found, for example, in the specification at page 4, lines 11-16; page 5, lines 20-21, page 7, lines 18-19; and page 8, lines 1-2, and 20.

Support for new claims 34-62 can be found throughout the specification and in the claims as originally filed. In particular, support for new claims 34 and 59 can be found, for example, in the specification at page 4, lines 1-6 and 11-17; page 5, line 8; page 6, lines 1-5; page 8, lines 5-10; page 10, lines 3, 11 and 19; page 11, lines 6 and 15. Support for new claims 35 and 60 can be found, for example, in the specification at page 4, line 7; page 5, line 8; page 6, lines 1-5; page 8, lines 5-10; page 10, lines 3, 11, and 19; and page 11, lines 6 and 15. Support for new claims 36 and 61 can be found, for example, in the specification at page 1, lines 15-17; page 1, line 20 to page 2, line 1; page 4, line 8; page 5, line 8; page 6, lines 2-3; page 7, lines 11 and 16; page 8, lines 21-22; page 9, lines 7 and 15; and page 10, lines 1, 10, and 19-20. Support for new claims 37 and 62 can be found, for example, in

the specification at page 1, line 20 to page 2, line 2; page 2, lines 7-8 and 14-15; page 4, line 8, page 5, line 8; page 6, lines 2-3; page 7, lines 11 and 16; page 8, lines 21-22; page 9, lines 7 and 15; and page 10, lines 1, 10, and 19-20. Support for new claim 38 can be found, for example, in the specification at page 4, lines 10-16; page 6, lines 4-5; page 8, lines 13-14; page 9, lines 5, 13, and 22; and page 10, lines 9 and 18. Support for new claim 39 can be found, for example, in the specification at page 4, lines 10-16; page 6, lines 4-5; and page 8, lines 13-14. Support for new claim 40 can be found, for example, in the specification at page 4, lines 10-16; page 6, lines 4-5; and page 8, lines 13-14. Support for new claims 41, 52, and 53 can be found, for example, in the specification at page 5, line 21 to page 6, line 6; page 7, lines 9-12; page 8, lines 12-13 and 16; page 9, lines 5, 13, and 21; and page 10, lines 8 and 17. Support for new claims 42, 54, and 55 can be found, for example, in the specification at page 5, line 21 to page 6, line 6; page 7, lines 9-12; page 8, lines 12-13 and 16; page 9, lines 5, 13, and 21; and page 10, lines 8 and 17. Support for new claims 41-43 and 52-57 can be found, for example, in the specification at page 5, line 21 to page 6, line 6; page 7, lines 9-12; page 8, lines 12-13 and 16; page 9, lines 5, 13, and 21; and page 10, lines 8 and 17. Support for new claims 44-51 can be found, for example, in the specification at page 7, lines 3-13 and page 8, lines 16-17.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections, and that they be withdrawn.

Objection to the Specification

The Examiner objected to the disclosure because "on pages 4, 7, lines 16 and 13, '98 DC to about 100 DC' and '160 DC' are written; on pages 9, 10 lines 5, 10, 11, 22, a symbol '~' is used in front of 2h or 100°C or 5h or 7h." (Paper No. 4, page 2). The specification has been amended to reflect the correct symbol for degrees Celsius and to replace the symbol "~" with the word "about." Accordingly, the Examiner's objections are rendered moot, and Applicants respectfully request that the objections to the specification be withdrawn.

Objection to the Claims

The Examiner objected to claims 4, 5, 16, and 17 because "a term 'zeolyte' is used.. [sic] Appropriate spelling correction is required." (Paper No. 4, page 2). The claims have been amended to reflect the correct spelling of "zeolite." Accordingly, the Examiner's objection has been rendered moot, and Applicants respectfully request that the objections to claims 4, 5, 16, and 17 be withdrawn.

Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1, 2, 4, 6, 13, 14, 16, 18, and 33 under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable one skilled in the art to include all the anhydrosugar alcohols, acid catalysts, soluble acids, zeolite powders, or acidic ion exchange resins unrelated to the invention commensurate in scope with these claims. (See Paper No. 4, pages 2-4). Claims 2 and 14 have been canceled, thereby rendering the Examiner's rejections moot with respect to those claims.

With respect to anhydrosugar alcohols, the Examiner contends that

Claims 1, 2, 4, 6, 13, 14, 16, 18, and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an anhydrosugar alcohol, such as, arabinitol, ribitol [sic], D-mannitol, galactitol, iditol, 1,5:3,6-dianhydrohexitols, 1,4:3,6-dianhydrohexitols, D-glucitol and etc. does not reasonably provide enablement for all the anhydrosugar alcohols known in the field of organic chemistry.

(Paper No. 4, page 2). Applicants respectfully disagree with the Examiner's contention.

The Manual of Patent Examining Procedure ("M.P.E.P.") indicates that it is incumbent upon the Examiner to establish a *prima facie* case of lack of enablement. *See* M.P.E.P. § 2164.04 (February 2003). Specifically, the M.P.E.P. states that:

The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done *by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact.*

Id. (underline in original) (italics added).

In the present case, the Examiner has merely concluded that the specification "does not enable any person skilled in the art . . . to include all the anhydrosugar alcohols unrelated to the invention commensurate in scope with these claims," without providing any reasons to support such a conclusion. (*See* Paper No. 4, page 2). According to the M.P.E.P., while "[r]eferences should be supplied if possible to support a *prima facie* case of lack of enablement. . . specific technical reasons are *always* required." M.P.E.P. § 2164.04 (citing *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)) (emphasis added).

Therefore, the Examiner has not met his burden of establishing a *prima facie* case of lack of enablement. Nevertheless, Applicants provide the following comments.

Applicants first point out that this rejection is not relevant to claim 33, which recites a process for the production of purified isosorbide using sorbitol as a starting material. Applicants also point out that the Examiner appears to have combined the representative examples of sugar alcohol starting materials, listed at page 4, lines 1-6, of the specification and two examples of anhydrosugar alcohols, referring to all as "anhydrosugar alcohols." Solely in an effort to facilitate prosecution, Applicants have amended claims 1 and 13 (and, therefore, their respective dependent claims) such that they recite a pentite or hexite sugar alcohol or monoanhydrosugar alcohol starting material.

With respect to acid catalysts, the Examiner asserts that

The specification, while being enabling for an acid catalyst, such as sulfuric acid, phosphoric acid, p-toluenesulfonic acid, p-methanesulfonic acid, and etc. does not reasonably provide enablement for all the acid catalysts in the field of chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the acid catalysts unrelated to the invention commensurate in scope with these claims.

(Paper No. 4, page 3). The Examiner further asserts that, under *Ex parte Sizto*, 9 USPQ2d 2081 (BPAI. 1988), "an acid catalyst composition represent[s] an unpredictable aspect in the art of organic chemistry." (Paper No. 4, page 3). Applicants respectfully disagree with the Examiner's assertions.

Applicants respectfully assert that *Sizto* is inapposite to the present application. In *Sizto*, the Examiner rejected claims that were directed to catalysts in general, asserting that the only example in the specification was to enzyme catalysts. *Sizto*, 9 USPQ2d at 2083. Thus, the Board of Patent Appeals and Interferences found that enablement for catalysts

other than enzyme catalysts was lacking, and agreed with the Examiner that "where the enzyme and non-enzyme catalysts are so divergent, it is not unreasonable to require a reasonable number of examples in support of the broad claim." *Id.* The Board, while finding that there was unpredictability as to the characteristics of catalyst conjugates formed from metal complexes and electron transfer agents as compared to enzymes, did *not* find that catalysts, and in particular, acid catalysts, are unpredictable *per se*.

Unlike in *Sizto*, the present claims recite an acid catalyst, and, as recognized by the Examiner on pages 3-4 of Paper No. 4, the specification provides examples not only of various classes of acid catalysts useful in the practice of the present invention (*see, e.g.*, specification, page 4, lines 20-22), but also non-limiting, representative examples of acid catalysts within those classes. (*See, e.g.*, specification, page 4, line 22 to page 5, line 8.) In addition, the Examiner is reminded that "[i]t is well settled that patent applications are not required to disclose every species encompassed by their claims, *even in an unpredictable art.*" *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991) (emphasis added). Nevertheless, solely to expedite prosecution, Applicants have amended claim 1 (and, therefore, its dependent claims) to recite a solid acid catalyst.

Furthermore, claim 13 has been amended to recite an acid catalyst selected from the group consisting of sulfuric acid, phosphoric acid, p-toluenesulfonic acid, p-methanesulfonic acid, and solid acid catalysts. The Examiner has specifically recognized that the specification is enabled for sulfuric acid, phosphoric acid, p-toluenesulfonic acid, p-methanesulfonic acid (*see* Paper No. 4, page 3), and Applicants assert that a representative number of species of solid acid catalysts encompassed by the scope of the present invention have been disclosed. (*See, e.g.*, specification, page 4, line 20 to page 5, line 8.)

With respect to soluble acids, the Examiner asserts that

The specification, while being enabling for a soluble acid, such as sulfuric acid, phosphoric acid, p-toluenesulfonic acid, p-methanesulfonic acid, and etc. does not reasonably provide enablement for all the soluble acids in the field of chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the soluble acids unrelated to the invention commensurate in scope with these claims. . . . Furthermore, there are "foreman factors or Wands factors" regarding unpredictability because a soluble acid includes any heterocyclic acid, any aromatic acid, any alicyclic acid, and a diverse scope of acyclic acids. In addition, it does not exclude any bi-functional acid such as a variety of amino acids. Moreover, more than routine experimentation is involved.

(Paper No. 4, pages 3-4; emphasis in original.) Applicants respectfully disagree with the Examiner's assertion.

Applicants point out that claims 16, 18, and 33 do not recite a soluble acid. Furthermore, Applicants have amended claim 1 (and, therefore, dependent claims 4 and 6) to recite a solid acid catalyst. Therefore, the Examiner's rejection has been rendered moot with respect to claims 1, 4, 6, and is not relevant to claims 16, 18, and 33. In addition, Applicants have amended claim 13 (and, therefore, its dependent claims) to recite an acid catalyst selected from the group consisting of sulfuric acid, phosphoric acid, p-toluenesulfonic acid, p-methanesulfonic acid, and solid acid catalysts. The Examiner has specifically recognized that the specification is enabled for the soluble acids sulfuric acid, phosphoric acid, p-toluenesulfonic acid, p-methanesulfonic acid.

With respect to zeolite powders, the Examiner contends that

The specification, while being enabling for a zeolite powder, such as CBV 3024, CBV 5534G, T-2665, or T-4480, and etc. does not reasonably provide enablement for all the a [sic] zeolite powder[s] in the field of chemistry. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the zeolite powder[s] unrelated to the invention commensurate in scope with these claims.

(Paper No. 4, page 4). Applicants respectfully disagree with the Examiner's contention.

As stated, *supra*, the M.P.E.P. indicates that it is incumbent upon the Examiner to establish a *prima facie* case of lack of enablement "by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact." See M.P.E.P. § 2164.04 (February 2003). In the present case, the Examiner has merely concluded that the specification "does not enable any person skilled in the art . . . to include all the zeolite powder[s] unrelated to the invention commensurate in scope with these claims," without providing any reasons to support such a conclusion. (See Paper No. 4, page 4). According to the M.P.E.P., while "[r]eferences should be supplied if possible to support a *prima facie* case of lack of enablement. . . specific technical reasons are *always* required." M.P.E.P. § 2164.04 (citing *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)) (emphasis added). Therefore, the Examiner has not met his burden of establishing a *prima facie* case of lack of enablement. Nevertheless, Applicants provide the following comments.

Applicants first point out that the Examiner's rejection is not relevant to claims 6, 18, and 33 because they are not directed to a zeolite powder. Applicants also respectfully assert that, since the claims recite an *acid* catalyst, one of ordinary skill in the art, based on the guidance and teachings in the specification, would be aware of the zeolite powders encompassed by the claims. Nevertheless, solely to expedite prosecution Applicants have amended claims 4 and 16 to recite an acidic zeolite powder. The specification provides a

representative number of non-limiting examples of acidic zeolite powders. *See e.g.*, specification at page 5, lines 1-4.

With respect to acidic ion exchange resins, the Examiner asserts that

The specification, while being enabling for an acidic ion exchange resin, such as AG50W-X12, Amberlyst 15 or 35, or Dowex 50Wx4, and etc. does not reasonably provide enablement for all the soluble acids^[1] in the field of organic chemistry. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to include all the acidic ion exchange resins unrelated to the invention commensurate in scope with these claims.

(Paper No. 4, page 4).

The Examiner further asserts that

...there are the "foreman factors or wands factors" regarding unpredictability because ion-exchange resins include cationic exchangers and anionic exchangers and furthermore, they contain various types of ion-exchange resins such as gel type, porous type, high porous type, liquid type, and solid type. Because of the diverse scopes of their unique compositions and variations of physical structures, their corresponding catalytic activities are unpredictable. Therefore, more than routine experimentation is required and involved (second foremen factor).

(Paper No. 4, page 4) (emphasis in original). Applicants respectfully disagree with the Examiner's assertion.

According to the Federal Circuit, "[i]t is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art." *In re Vaeck*, 947 F.2d 488, 496; 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991) (citing *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q. 214, 218 (CCPA 1976)). Rather, "the

¹Applicants query whether Examiner meant to write "acidic ion exchange resins" instead of "soluble acids."

disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." *Id.* "That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'" *Id.* at 495, 20 USPQ2d at 1445 (citing *In re Wands*, 858 F.2d 731, 736-737, 8 USPQ2d (BNA) 1400, 1404 (Fed. Cir. 1988)) (emphasis in original). Factors that may be considered in determining whether experimentation is "undue" were set forth in *Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404. Among these factors are: the amount of effort involved, the guidance provided by the specification, the presence of working examples, and the level of skill in the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. *See id.*

Wands involved an appeal from the Board of Appeals and Patent Interferences, affirming the examiner, rejecting immunoassay claims on the grounds that making anti-HBsAg antibodies for use in the claimed immunoassay, other than the deposited antibody, would be "unpredictable and unreliable, so that it would require undue experimentation for one skilled in the art to make the antibodies." *Id.* at 735, 8 USPQ2d at 1402. Antibodies other than the one deposited were described only in terms of function and only a general method of making and using them was disclosed in the application. *See id.* The facts showed that IgM antibodies were disfavored because they tended to self-aggregate and precipitate, isolating the correct antibodies required screening hundreds of clones, and the appellant's first four attempts were unsuccessful. *See id.* at 734, 8 USPQ2d at 1402. Nevertheless, the Federal Circuit found that the disclosure satisfied the requirements under § 112, first paragraph. The court based its decision on the fact that the invention could be

practiced with "readily available starting materials using methods that are well known in the monoclonal antibody art" and because "practitioners of the art are prepared to screen negative hybridomas in order to find one that makes the desired antibody." *See id.* at 736, 8 USPQ2d at 1406.

Contrary to the Examiner's assertions, the claims of the present invention recite only an acidic ion exchange resin. Applicants respectfully assert that the properties of acidic ion exchange resins are well known in the art; therefore, there is greater predictability with respect to the acidic ion exchange resin than the Examiner suggests. For example, page 1933 of the 1999 Sigma Catalog (attached hereto as Exhibit A) lists the properties of various acidic ion exchangers. Furthermore, while the predictability of the art can be considered in determining whether an amount of experimentation is undue, mere unpredictability of the result of the experiment is not a consideration. Indeed, in *In re Angstadt*, the Court of Custom and Patent Appeals specifically cautioned that the unpredictability of the result of an experiment is not a basis to conclude that the amount of experimentation is undue:

[If to fulfill the requirements of 112, first paragraph, an applicant's] disclosure must provide guidance which will enable one skilled in the art to determine, with reasonable certainty before performing the reaction whether the claimed product will be obtained, . . . then all "experimentation" is "undue" since the term "experimentation" implies that the success of the particular activity is uncertain. Such a proposition is contrary to the basic policy of the Patent Act.

537 F.2d at 503, 190 USPQ at 219 (emphasis in original).

In the current application, the specification and the knowledge in the art provide sufficient information such that the skilled artisan can practice the invention. In the specification, Applicants have recited in detail how to make and use each aspect of the claimed invention. Applicants have even provided working examples (which are not

required) demonstrating that the claimed invention is effective. More specifically, Applicants have shown in the Examples the use of acidic ion exchange resins as acid catalysts in the production of anhydrosugar alcohols from sugar alcohol starting materials.

In view of Applicants' amendments and/or remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 4, 6, 13, 16, 18, and 33 under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 1, 13, and 33 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (Paper No. 4, page 5). Specifically, the Examiner contends that "[a] phrase 'organic solvents' is written. However, this does not specify what types of solvents are not employed in the process." *Id.* Applicants respectfully disagree with the Examiner's contention.

The definiteness requirement "requires the language of the claim to set forth clearly the domain over which the applicant seeks exclusive rights." *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 n.2, 52 USPQ2d 1029, 1034 n.2 (Fed. Cir. 1999). Further, "[t]he test for whether a claim meets the definiteness requirement is 'whether one skilled in the art would understand the bounds of the claim when read in light of the specification.'" *Process Control*, 190 F.3d at 1358 n.2, 52 USPQ2d at 1034 n.2 (quoting *Personalized Media Communications v. Int'l Trade Comm'n*, 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed. Cir. 1998)). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Miles*

Laboratories, Inc. v. Shandon Inc., 997 F.2d 870, 875 (Fed. Cir. 1993), *cert. denied*, 510 U.S. 1100 (1994) (citations omitted). Applicants submit that the claims, when read in light of the specification, reasonably apprise one skilled in the art of the metes and bounds of the claimed invention.

Claims 1, 13, and 33 and the specification indicate that no organic solvents are used. See specification at page 2, line 23 to page 3, line 2, and page 3, lines 6-7. Applicants respectfully submit that it is not necessary to list individually the vast numbers of organic solvents that are not used because one of ordinary skill in the art would know the difference between an organic and a non-organic solvent, and would be aware that "without using organic solvents" means that no organic solvent is used in the claimed invention.

The Examiner also asserts that "[a] phrase 'maintaining-temperature' is written. However, this does not specify what temperature the dehydrating process is conducted." (Paper No. 4, page 5.) Applicants submit that claim 33 complies with the requirements of 35 U.S.C. § 112, second paragraph. Nevertheless, claim 33 has been amended to recite "maintaining. . .temperature of from about 98°C to about 191°C."

The Examiner further contends that "[a] phrase 'a slurry-like isosorbide solution' is written. However, this does not explain what is the meaning of 'a slurry-like isosorbide solution.'" (Paper No. 4, page 5.) Applicants assert that claim 33 is clear with respect to what is meant by "a slurry-like isosorbide solution." In particular, the specification at page 7, lines 15-19, for example, specifically describes a slurry-like isosorbide solution. However, solely to expedite prosecution, Applicants have amended claim 33 to recite "an isosorbide solution having a slurry-like consistency" to further clarify for the Examiner what is meant by "a slurry-like isosorbide solution."

The Examiner also asserts that "[a] phrase '35D C' is written. This is vague and there is no meaning of the symbol." (Paper No. 4, page 5). Applicants have amended claim 33 to replace the "□" symbol with the "o" symbol to indicate degrees Celsius. As described above with respect to the Examiner's objections to the specification, this would be clearly recognized by one of skill in the art as a typographical error, as would the correction of the symbol.

The Examiner's grounds of rejection of claims 1, 13, and 33 under 35 U.S.C. § 112, second paragraph, have been addressed by Applicants' amendments and/or remarks. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

Rejections under 35 U.S.C. § 102

The Examiner rejected claims 1-3 and 10 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 3,454,603 to Hartmann. (*See* Paper No. 4, page 6.) In particular, the Examiner asserts that

Hartmann discloses a process of preparing 1,4-3,6-dihydroxyglucitol by heating hexitols, such as 1,4 D,L-allitan or 1,4 D,L-dulcitan, in the presence of an acid dehydration catalyst, such as sulfuric acid, p-toluenesulfonic acid (see col. 2, lines 25-40), and then distilling the reaction mixture to recover dihydrohexitols at extremely low pressures (below 1.0 mmHg) (see col. 2, lines 59-61). In addition, the products may be further purified by redistillation (see col. 2, line 69).

(Paper No. 4, page 6.)

Anticipation of a claim under section 102 can be found only if the prior art reference discloses each and every element as set forth in the claim. *See Glaxo Inc. v. Novopharm*

Ltd., 34 USPQ2d 1565, 1567 (Fed. Cir. 1995), *cert denied*, 116 S. Ct. 516 (1995). Further, "[a]n anticipating reference must describe the . . . [claimed] subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention." *ATD Corp. v. Lydall Inc.*, 48 USPQ2d 1321, 1328 (Fed. Cir. 1998). Therefore, in order for the Hartmann reference to anticipate the claimed invention, it must describe each and every limitation of Applicants' claimed invention such that the subject matter would be recognized by one skilled in the art.

Claims 2 and 3 have been cancelled, thereby rendering the Examiner's rejection moot with respect to those claims. Claim 1 (and, therefore, claim 10, which depends directly from claim 1 and thereby incorporates all of the limitations of claim 1) has been amended to recite a solid acid catalyst. Hartmann does not teach the use of a solid acid catalyst. Rather, as recognized by the Examiner, Hartmann describes the use of sulfuric acid and p-toluenesulfonic acid as acid catalysts. (*See* Paper No. 4, page 6.) Since the Hartmann reference does not disclose each and every element of the claimed invention, Applicants respectfully request that the rejection of these claims under 35 U.S.C. § 102 (b) be withdrawn.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 1-33 under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Hartmann, U.S. Patent No. 3,454,603 in view of Feldmann *et al.*, U.S. Patent No. 4,564,692 and Brinegar *et al.*, PCT Publication No. WO 00/14081. (*See* Paper No. 4, page 7.) The Examiner acknowledges that

[t]he instant invention differs from Hartmann in that melt crystallizing, filtering, and centrifuging the anydrosugar alcohol are unspecified; the acidic ion exchange resin is added in an amount of from 0.01 to 0.15 gram equivalents to sugar alcohol; the acid catalyst contains a zeolite powder selected from CBV 3024, CBV 5534G, AG50W-X12^[2]; the period is from 30 to 45 minutes during the cooling.

(Paper No. 4, page 8). However, the Examiner asserts that

[w]it[h] respect to the use of the acid catalyst containing the zeolite powder selected from CBV 3024, CBV 5534G, AG50W-X12^[3], the prior art references are silent. However, it is well-known in the art that AG50W-X12 acidic catalyst can be used with an advantage of little or no residue in producing anhydro sugar alcohols as shown in Brinegar et al (see page 7, lines 5-6). Therefore, it would have been obvious to the skilled artisan in the art to have motivated to use the Brinegar et al AG50W-X12 as a substitute. This is because the skilled artisan in the art would expect to improve on the purity of the desired compound by using the AG50W-X12 catalyst in the process.

(Paper No. 4, page 9.) The Examiner further asserts that

Feldmann et al expressly teaches the process of purifying the anhydro sugar alcohols obtained from acid-catalyzed dehydration of hexitols by crystallization from a concentrated solution in the absence of organic crystallization solvents; moreover, when sugar alcohols are dehydrated, the reaction mixtures contain various impurities detrimental to the production of polyesters (see col. 1, lines 23-30). Therefore, it would have been obvious to the skilled artisan in the art to have motivated to incorporate the Feldmann et al crystallization technique into Hartmann in order to further purify the desired product suitable for producing polyesters.

(Paper No. 4, pages 9-10.) Applicants respectfully traverse this rejection.

²Applicants point out that AG50W-X12 is not a zeolite powder; rather, it is an acidic ionic exchange resin. *See* specification at page 5, lines 4-5.

³*See* footnote 2, *supra*.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness. Among other requirements, in order to establish a *prima facie* case of obviousness there must be some suggestion or motivation to combine the reference teachings. *See, e.g.*, M.P.E.P. § 2143 at 2100-124-2100-125 (8th ed., Rev. 1, Feb. 2003). Obviousness cannot be established by modifying the teachings of the prior art to produce the claimed invention unless there is some teaching, suggestion or motivation to do so found either in the reference itself or in the knowledge generally available to one of ordinary skill in the art. *See In re Fine*, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). In addition, the mere fact that a reference could conceivably be modified to make the claimed invention does not render the resultant modification obvious unless the prior art also suggests the desirability of that specific modification. *See In re Mills*, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990).

Brinegar *et al.* teaches a continuous process for the production of anhydrosugar alcohols *using an organic solvent*, wherein the solvent can be recycled during the process. *See e.g.*, Brinegar *et al.*, page 1, lines 15-21. However, Brinegar *et al.* does not suggest the desirability or feasibility of a process for the production of anyhydrosugar alcohols without the use of organic solvents. Thus, the fact that a process for the production of anhydrosugar alcohols using AG50W-X12 as an acid catalyst and without using organic solvents is conceivable, as demonstrated by Applicants, does not render the claimed invention obvious over the cited references since they fail to provide the requisite suggestion.

Furthermore, the purification process of Feldmann *et al.* is a supersaturation-based method that uses seed crystals. Therefore, even assuming there were, as the Examiner suggests, a motivation "to incorporate the Feldmann *et al* crystallization technique into Hartmann in order to further purify the desired product suitable for producing polyesters,"

(Paper No. 4, pages 9-10), such a combination does not teach or suggest the present invention, which does not use seed crystals in a supersaturation-based purification method.

In view of the above, Applicants submit that the cited references do not suggest the desirability of combining the references to obtain the claimed invention, and thus fail to render the claimed invention obvious. Consequently, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 103 (a) be withdrawn.

Other Matters

The Examiner listed as art made of record but not relied upon: Salzburg *et al.*, U.S. Patent No. 4,408,061; Hartmann, U.S. Patent No. 3,160,641; Salzburg *et al.*, U.S. Patent No. 4,506,086; Leuders *et al.*, U.S. Patent No. 4,861,513; and Stockburger, U.S. Patent No. 4,297,290. (Paper No. 4, pages 10-11.)

Applicants thank the Examiner for signing off on the references listed on the Form PTO-1449 submitted with Applicants' Information Disclosure Statement, filed February 13, 2002. However, the Examiner inadvertantly included a copy of a Form PTO-1449 from a different application with the Office Action dated March 4, 2003. In a telephone conversation with Tracy Muller on May 29, 2003, the Examiner requested that the incorrect Form PTO-1449 be attached to this Reply, and indicated that the correct copy of the Form PTO-1449 submitted with Applicant's First Supplemental Information Disclosure Statement, filed November 1, 2002, would be sent with the next Office Action. In accordance with the Examiner's request, attached is the Form PTO-1449 that was sent to Applicants by mistake.


Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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